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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,150	06/25/2003	Birgit K. Jaitner	59516-275/PP-18707.002.	1248

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EXAMINER	
MCGARRY, SEAN	
ART UNIT	**PAPER NUMBER**
1635	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/609,150	JAITNER ET AL.	
	Examiner	Art Unit	
	Sean R. McGarry	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *7,12-16 and 20-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 8-11, 17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 8, 10, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by McKay et al [US 6,455,307].

McKay et al disclose SEQ ID NO: 93 which is a 20mer antisense oligonucleotide that comprises at least 10 consecutive nucleic acids of the sequence of the instant SEQ ID NO:1. The oligonucleotide of McKay et al corresponds to residues 3435-3452 of SEQ ID NO: 1. The oligonucleotide is disclosed in a composition comprising pharmaceutically acceptable carriers. The disclosure of McKay et al meets all of the structural requirements of the claimed invention.

Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

"[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is

based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald,* 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best,* 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

Applicant's arguments filed 7/25/06 have been fully considered but they are not persuasive. Applicant argues that McKay do not teach an oligonucleotide that "specifically hybridizes" to Sos1 mRNA. Applicant points to page 9, lines 1-4 and page 46, lines 9-11 as support and as evidence that the prior art does not read on the instant invention. First it is noted that claims 8, 10 and 17 do not recite such a limitation and applicant offers no argument for patentability for these claims. Second, it is noted that the instant specification does not provide a specific definition for "specifically hybridizes". It is the opinion of the examiner that the oligonucleotide of McKay would specifically hybridize with Sos1 in the absence of a casein kinase 2-alpha mRNA.

Claims 8, 10,18, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Schweighoffer et al [US 5,656,595].

Schweighoffer et al have disclosed a nucleic sequence [SEQ ID NO: 5, see column 10, for example] that corresponds to the SOS1 sequence of the instant invention [SEQ ID NO:1]. Schweighoffer et al disclose several SOS1 inhibitors including antisense molecules made of or from SEQ ID NO: 5. At column 3 it is disclosed antibodies, for example. It is disclosed at column 4 that antisense

oligonucleotides can be made from all of or a part of SEQ ID NO: 5. It is disclosed that such sequences can be expressed from vectors (see column 4, for example). It is also disclosed at columns 3-4 that the inhibitors are for therapeutic purposes. All of SEQ ID NO: 5 is more than 10 nucleotides. SEQ ID NOS: 2 and 3 are comprised within SEQ ID NO: 5, and would inherently be in an antisense molecule that utilizes all of SEQ ID NO: 5, for example. It is noted that the claims are not limited to antisense oligonucleotides that are SEQ ID NO: 2 or 3 but limited only to comprising 2 or 3 and further there is no limit to the oligonucleotide length in the claims that recite SEQ ID NOS 2 and 3. The claims as amended [claims 18 and 19 now only require that the claimed nucleic acid have contiguous nucleotides of SEQ ID NO: 2 or 3. It is noted that contiguous includes two contiguous nucleotides of SEQ ID NO 2 or 3.

Applicant's arguments filed 7/25/06 have been fully considered but they are not persuasive. Applicant argues that Schweighoffer et al do not teach an oligonucleotide that "specifically hybridizes" to Sos1 mRNA. It is noted that claims 8, 10, 18, and 19 do not recite the limitation applicant rlies upon to overcome the prior art.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 8-11, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schweighoffer et al in view of McKay et al.

Schweighoffer et al have disclosed a nucleic sequence [SEQ ID NO: 5, see column 10, for example] that corresponds to the SOS1 sequence of the instant invention [SEQ ID NO:1]. Schweighoffer et al disclose several SOS1 inhibitors including antisense molecules made of or from SEQ ID NO: 5. At column 3 it is disclosed antibodies, for example. It is also disclosed at columns 3-4 that the inhibitors are for therapeutic purposes. It is disclosed at column 4 that antisense oligonucleotides can be made from all of or a part of SEQ ID NO: 5. It is disclosed that such sequences can be expressed from vectors. All of SEQ ID NO: 5 is more than 10 nucleotides. SEQ ID NOS: 2 and 3 are comprised within SEQ ID NO: 5, and would inherently be in an antisense molecule that utilizes all of SEQ ID NO: 5, for example. It is noted that the claims are not limited to antisense oligonucleotides that are SEQ ID NO: 2 or 3 but limited only to comprising 2 or 3and further there is no limit to the oligonucleotide length in the claims that recite SEQ ID NOS 2 and 3. Schweighoffer et al do not specifically teach ribozyme inhibitors and do not specifically teach using more than one inhibitor and do not specifically teach antisense oligonucleotides that are 8 to 35 nucleotides in length.

McKay et al have taught in general terms at columns 4-8, for example, the use of and design of antisense oligonucleotides. It has been taught, at column 7, that antisense oligonucleotides can be 8-50 or 12 to 30 nucleobases in length. It is taught at column 7, that ribozymes are antisense molecules and would therefore be obvious

equivalents of non-catalytic antisense molecules. At columns 27-28 it is disclosed the use of various inhibitors in combination with an antisense oligonucleotide. McKay also teach at columns 3-4, the concept of "specifically hybridizing" with antisense oligonucleotides.

It would have been obvious to combine the teachings above to make the claimed invention. Schweighoffer et al have taught antisense as well as other inhibitors of SOS1. McKay et al have taught size preferences for antisense oligonucleotides and have taught that ribozymes are antisense compounds. McKay et al have also taught to use more that one inhibitor compound in a composition that may be used as an inhibitory composition and to make antisense that "specifically hybridize" with their target nucleic acid.

The claimed invention as a whole would therefore have been *prima facie* obvious to one in the art at the time the invention was made.

Applicant's arguments filed 7/25/06 have been fully considered but they are not persuasive. Applicant argues that McKay do not teach an oligonucleotide that "specifically hybridizes" to Sos1 mRNA. It is noted that at columns 3-4 the concept of "specifically hybridizing" is discussed in McKay and in combination with Schweighoffer the specific hybridization of Sos1 antisense to a target is indeed obvious. Applicant offers no other arguments.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean R McGarry
Primary Examiner
Art Unit 1635